**Contact Information**

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| **Principal Investigator:** |  | **Person Completing This Form:** | |  |
| **Institutional Affiliation:** |  | **Anonymous: If Yes, please check** | |  |
| **IRB Protocol Number:** |  | **Date Submitted:** | |  |
| **May we reveal your name to the Investigator:**   Yes  No | | |  | |

**Complaint/Concern Information**

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| **Instructions:** Upon completion, please email this form to research@mayinstitute.org. This form may also be either faxed to the IRB at 781-440-0401 or sent by mail to: Human Research Protections Program, 41 Pacella Park Dr., Randolph, MA, 02368. |
| 1. **If not anonymous, how was the information disclosed?** |
| Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other Contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Is this report being made on behalf of someone else?**   Yes  No  If “yes”, please provide a brief explanation: |
|  |
| 1. **Is this complaint associated with a study?**   Yes  No   If “yes,” please tell us the title of the study or provide a summary. Any information will be helpful. |
|  |
| 1. **Please describe your complaint or concern:** |
|  |
| 1. **How would you like this complaint or concern resolved?** |
|  |
| 1. **Have you contacted the Principal Investigator or study staff?**  Yes  No Name of the person contacted: |
|  |
| 1. **Are you or were you a participant in this study?**   Yes  No |
| 1. **Did you receive a consent document?**   Yes  No |
| 1. **Have you previously reported this complaint?**  Yes  No |
| 1. **Please provide any additional information:** |
|  |

**HRPP Use Only**

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| **Actions Taken:**   Notified IO  Investigation Initiated  Referred to Convened Board  Notified other Sources  **Level of Risk of the study:**   Minimal Risk  More than Minimal Risk  **Unresolved Research Complaint**:  Yes  No |
| OHRP Staff Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |